

REMARKS/ARGUMENTS

Claims 1-20 are pending in the application. Claims 1-20 are subject to restriction and/or election requirement.

Claims 15-20 have been canceled and re-written as new claims 21-26 in order to conform them to U.S. practice as requested by the Examiner.

Restriction is required between the following Groups of inventions:

Group I, claims 1-14, drawn to a composition comprising an opioid analgesic, a 1-(1,2-disubstituted piperidinyl)-4-substituted piperazine derivative, and a pharmaceutically acceptable carrier.

Group II, claims 15-20, drawn to method of using the composition.

Applicants elect the subject matter of the Examiner's Group I for further prosecution of this application. Applicants have been requested to elect one specific species from the generic chemical structure Formula (I) set forth in claim 1. Applicants elect as the specific species the following compound:

(B)-trans-4-[1-[3,5-bis(trifluoromethyl)benzoyl]-2-(phenylmethyl)-4-piperidinyl]-N-(2,6-dimethylphenyl)-1-piperazine acetamide, (L)-malic acid.

In addition to the election of a piperazine derivative applicants have been requested to elect one species from the different opioid analgesics. Applicants elect fentanyl as the specific opioid species. Claims 1, 8, 10, 11, 12, 13 and 14 read on the elected species.

The above elections were made with traverse.

In requiring restriction between Groups I and II the Examiner has concluded that the Groups do not relate to a single general inventive concept under PCT Rule 13 because they lack the same or corresponding special technical features in that the instant claim 1 lacks an inventive step over U.S. patent 5,880,132 which teaches a composition comprising a tachykinin antagonist, an opioid analgesic and a pharmaceutically acceptable carrier in light of U.S patent 6,197,772B1 which teaches substituted piperazine derivatives having tachykinin antagonistic activity. The Examiner has concluded that the instant claim 1 does not share technical features with the instant claims 15-20 (Group II) therefore resulting in a lack of unity between the two groups.

Applicants invention relates to pharmaceutical formulations for opioid based treatments of pain an/or nociception comprising opioid analgesics and certain piperazine derivatives having neurokinin antagonistic activity in a pharmaceutically acceptable carrier. The claimed compositions reduce to a large extent the unwanted side-effects associated with opioid analgesics, see specifically the Pharmacological Examples beginning on page 51 related to the elected compound. Since the compounds employed in the formulations of Group I are the same compounds contained in the method of treatment claims of Group II, it is submitted that the examination of both Groups in the same application would not be unduly burdensome for the Examiner since the search for each Group would be essentially the same. It seems proper, therefore, to examine the formulations and the method of using the formulations in a single application.

Reconsideration of the Restriction Requirement under 35 USC §121 and §372 is courteously requested.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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